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## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION

REC'D 28 JUL 2004

REPORT

PCT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 12187260/TDO/LM	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. <b>PCT/AU2003/000403</b>	International Filing Date (day/month/year) <b>2 April 2003</b>	Priority Date (day/month/year) <b>2 April 2002</b>
International Patent Classification (IPC) or national classification and IPC <b>Int. Cl. 7 C07K 014/415; A61K 038/16; A61P 037/08</b>		
Applicant <b>MONASH UNIVERSITY et al</b>		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

I	<input checked="" type="checkbox"/> Basis of the report
II	<input type="checkbox"/> Priority
III	<input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	<input type="checkbox"/> Lack of unity of invention
V	<input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	<input type="checkbox"/> Certain documents cited
VII	<input type="checkbox"/> Certain defects in the international application
VIII	<input type="checkbox"/> Certain observations on the international application

Date of submission of the demand <b>3 October 2003</b>	Date of completion of the report <b>15 July 2004</b>
Name and mailing address of the IPEA/AU <b>AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929</b>	Authorized Officer  <b>R.L. POOLEY</b> Telephone No. (02) 6283 2242

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU2003/000403

**I. Basis of the report**

## 1. With regard to the elements of the international application:\*

the international application as originally filed.

the description, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of

the claims, pages , as originally filed,  
pages , as amended (together with any statement) under Article 19,  
pages , filed with the demand,  
pages , received on with the letter of

the drawings, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of

the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

the language of publication of the international application (under Rule 48.3(b)).

the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

contained in the international application in written form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4.  The amendments have resulted in the cancellation of:

the description, pages

the claims, Nos.

the drawings, sheets/fig.

5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU2003/000403

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims 7, 8, 11-16, 19, 20, 26, 27, 31-39	YES
	Claims 1-6, 9, 10, 17, 18, 21-25, 28-30, 40-47	NO
Inventive step (IS)	Claims	YES
	Claims 1-47	NO
Industrial applicability (IA)	Claims 1-47	YES
	Claims	NO

**2. Citations and explanations (Rule 70.7)**

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1: WO 1996/000238 A1 (PEPTIDE THERAPEUTICS LIMITED) 04 January 1996, see claims.

D2: Burton et al, J. Allergy Clin. Immunol., vol. 103, no. 2, part 1, 1999, pages 255-261, see page 256, column 1.

D3: WO 1997/005258 A2 (BIOMAY PRODUKTIONS) 13 February 1997, see abstract.

D4: Ball et al, FASEB Journal, 1999, Vol. 13(11), pages 1277-1290, see abstract.

D5: Eusebius et al, Int Arch Immunol 2002, Vol. 127, pages 234-244, see page 243, final paragraph.

**Novelty (N)**

Citation D1 discloses polypeptides including XVXRIDTX of Lol p 1, which is part of sequence ID number 24 of the current application. The citation also treats rye grass allergy by administration of said polypeptide. Thus claims 1, 3-6, 9, 17-18, 21-25, 28-30 and 40-47 lack novelty.

Citation D2 discloses Lol p 5, p105-116 with a view to identifying analogues that could be used as immunotherapeutic agents against rye grass pollen allergic disease. Claims 2, 10, 21 and 40-47 thus lack novelty.

Claims 7, 8, 11-16, 19, 20, 26, 27 and 31-39 relate to peptides containing amino acid sequences not specifically disclosed in the citations, and thus these claims are novel.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**Continuation of Box V****Inventive Step (IS)**

Citations D3-5 do not specifically disclose Lol p 1 or Lol p 5. They do however disclose epitopes of grass pollens and their use in immunotherapy against allergic reactions to said pollens. Given that Lol p 1 and Lol p 5 are well known to a person skilled in the art (see D1 and D2), no inventive faculty is required to use either epitope in the treatment or prevention of rye grass allergy. Citations D1 and D2 are particularly relevant as the use of one of Lol p 1 or Lol p 5 would easily lead a person skilled in the art to try the other. Thus all claims lack an inventive step when compared to citations D1-D5.

**Industrial Applicability (IA)**

All claims possess industrial applicability.